

**TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A SUBMISSION UNDER 35 U.S.C. 371**

PG4860

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

10/517801INTERNATIONAL APPLICATION NO.
PCT/EP2003/006465INTERNATIONAL FILING DATE
June 19, 2003PRIORITY DATE CLAIMED
June 19, 2002

TITLE OF INVENTION

**(2S)-2-AMINO-4-[[2-(ETHANIMIDOYLAMINO) ETHYL]THIO]BUTANOIC ACID, A NITRIC OXIDE SYNTHASE
INHIBITOR, IN STABILIZED PHARMACEUTICAL DOSAGE FORMS**

APPLICANT(S) FOR DO/EO/US

Stuart BROUGHTON et al.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below.
4. ☒ The US has been elected (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
 - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ has been communicated by the International Bureau.
 - c. ☒ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
 - a. ☐ is attached hereto.
 - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11. ☒ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☒ A copy of the International Search Report (PCT/ISA/210).

Items 13 to 23 below concern document(s) or information included:

13. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☒ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A power of attorney and/or change of address letter.
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
20. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
21. ☐ A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4).
22. ☒ Express Mail Label No. EV332064310 US
23. ☒ Other items or information:

PCT Request

PCT Coverpage of Publication

U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/517801	INTERNATIONAL APPLICATION NO. PCT/EP2003/006465	ATTORNEY'S DOCKET NUMBER PG4860
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24. The following fees are submitted:.

BASIC NATIONAL FEE (37 CFR 1.492(a)(1)-(5)) :

- | | | |
|-------------------------------------|---|-----------|
| <input type="checkbox"/> | Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO | \$1110.00 |
| <input checked="" type="checkbox"/> | International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO | \$950.00 |
| <input type="checkbox"/> | International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO | \$790.00 |
| <input type="checkbox"/> | International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) | \$750.00 |
| <input type="checkbox"/> | International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) | \$100.00 |

ENTER APPROPRIATE BASIC FEE AMOUNT =

\$950.00

Surcharge of **\$130.00** for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).

\$0.00

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	11 - 20 =	0	x \$18.00	\$0.00	
Independent claims	1 - 3 =	0	x \$88.00	\$0.00	
Multiple Dependent Claims (check if applicable).			<input type="checkbox"/>	\$0.00	

Multiple Dependent Claims (check if applicable).

TOTAL OF ABOVE CALCULATIONS =

\$950.00

- ☐ Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.

\$0.00

SUBTOTAL =

\$950.00

Processing fee of \$130.00 for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(f)).

\$0.00

TOTAL NATIONAL FEE =

\$950.00

Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) (check if applicable).

\$0.00

TOTAL FEES ENCLOSED =

\$950.00

Amount to be: refunded	\$
charged	\$

- a. ☐ A check in the amount of _____ to cover the above fees is enclosed.
- b. ☒ Please charge my Deposit Account No. 07-1392 in the amount of \$950.00 to cover the above fees.
- c. ☒ The Director is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 07-1392
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

CUSTOMER NUMBER
23347

Connie L. Leppenbrock
SIGNATURE


Bonnie L. Deppenbrock

NAME _____

28,209

REGISTRATION NUMBER

DATE _____

CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)			Docket No. PG4860	
Applicant(s): Stuart BROUGHTON, et al.				
Application No. To be assigned	Filing Date	Examiner	Customer No.	Group Art Unit
Invention: (2S)-2-AMINO-4-{{[2-(ETHANIMIDOYLAMINO) ETHYL]THIO}BUTANOIC ACID, A NITRIC OXIDE SYNTHASE INHIBITOR, IN STABILIZED PHARMACEUTICAL DOSAGE FORMS				
<p>I hereby certify that the following correspondence:</p> <div style="border: 1px solid black; padding: 10px; margin: 10px 0;"> Transmittal Letter to the DO/EO/US Concerning a Filing Under 35 U.S.C. 371 </div> <p style="text-align: center; font-size: small;">(Identify type of correspondence)</p> <p>is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on</p> <p style="text-align: center; margin-left: 100px;"> <u>December 10, 2004</u> <small>(Date)</small> </p> <div style="text-align: right; margin-top: 20px;"> <p>Julie D. McFalls</p> <p style="font-size: small;">(Typed or Printed Name of Person Mailing Correspondence)</p> <div style="margin-top: 10px;">  <small>(Signature of Person Mailing Correspondence)</small> </div> <div style="margin-top: 10px;"> <div style="border: 1px solid black; padding: 2px; display: inline-block;">EV332064310US</div> </div> </div>				
<p>Note: Each paper must have its own certificate of mailing.</p>				